

REMARKS

The pending Office Action addresses claims 1, 3-13, 15-26, 28, 29, 31-44, 46-54, and 86-93. Claims 25, 29, 32, 39-44, 47, and 49-54 are withdrawn. Claims 1, 3-8, 11, 12, 15-24, 26, 28, 31, 33, 34, 36, 37, 45, 46, 48, and 86-93 stand rejected. Applicants appreciate the Examiner's indication that claims 9, 10, 13, 35, and 38 represent allowable subject matter.

Claim Amendments

Claim 1 is amended to recite that the guide member has a first and second pathways formed therein for receiving a tool such that the first and second pathways in the guide member are aligned with a corresponding bore formed in the implant. No new matter is added.

Rejections Pursuant to 35 U.S.C. §102

(1) German Patent No. 4201043 of Ulrich.

Claims 91 and 93 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by German Patent No. 4201043 of Ulrich.

Ulrich does not teach a first guide member coupled to the distal end of a first arm, and a second guide member coupled to the distal end of a second arm, where *each* guide member has opposed cut-out portions formed therein, as required by independent claim 91. Ulrich teaches a device having two arms (22', 22''), each with a guide tube (21) attached thereto. The arms are mounted on a cross beam (23), as shown in FIG. 6. While each of the guide tubes (21) appears to include a single cut-out portion, neither of the guide tubes (21) include *opposed* cut-out portions. Claim 91 requires both guide members to include opposed (i.e., two) cut-out portions. Since the guide tubes (21) only include one cut-out portion each, Ulrich cannot anticipate the claimed invention.

Accordingly, independent claim 91, as well as claim 93 which depends therefrom, therefore distinguishes over Ulrich.

(2) *U.S. Patent No. 5,067,477 of Santangelo.*

Claims 86-90 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,067,477 of Santangelo.

Independent claim 86 requires first and second guide members, *each* having first and second pathways for receiving a tool and opposed tabs extending distally therefrom. Santangelo fails to teach first and second guide members as claimed. The arms in Santangelo include retractor blades (24) attached thereto that are inserted into a wound to spread tissue. As shown in FIG. 1 of Santangelo, the blades are similar in shape to hooks to allow the blades to hook to the tissue around the wound to be separated. The blades do not form a guide member with first and second pathways. Moreover, neither guide member includes opposed tabs extending therefrom. While the arms extend beyond the blades (24), claim 86 requires each guide member – not the arms – to include the tabs. The blades (24) of Santangelo do not include anything that can be considered to be a distally extending tab, much less two opposed tabs.

Accordingly, claim 86, as well as claims 87-90, which depend therefrom, distinguish over Santangelo.

(3) *U.S. Patent No. 7,147,599 of Phillips et al.*

Claims 1, 3, and 15-19 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,147,599 of Phillips et al.

Phillips fails to teach or suggest a guide member has first and second pathways formed therein, as required by claim 1. Phillips is directed to a retractor device that includes first and second arms. As shown in FIG. 1, each arm includes a hook portion formed on an end thereof. While the concave space formed by the hook portion can form a single pathway, there is certainly no second pathway formed in either of the arms of the retractor device. Thus, Phillips does not include a guide member that has first and second pathways formed therein and cannot anticipate the claim.

Accordingly, claim 1, as well as claims 3 and 15-19, which depend therefrom, distinguish over Phillips.

Rejections Pursuant to 35 U.S.C. §103

(1) U.S. Patent No. 7,147,599 of Phillips et al.

Claim 24 is rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,147,599 of Phillips et al. Claim 24 depends from claim 1, and thus distinguishes over Phillips for at least the same reasons discussed above. Claim 24 therefore represents allowable subject matter at least because it depends from claim 1.

(2) U.S. Patent No. 5,423,826 of Coates et al. in view of U.S. Patent No. 7,147,599 of Phillips et al.

Claims 1, 3-8, 11, 12, 15-23, 26, 28, 31, 33, 34, 36, 37, 46, and 48 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,423,826 of Coates et al. in view of U.S. Patent No. 7,147,599 of Phillips et al.

At the outset, Coates does not teach arms having a proximal end coupled to a support, as required by claim 1. Rather, the rod extends through a mid-portion of the arms. It does not mate to the proximal end of each arm. For the same reasons, Coates does not include a second arm having an end mated to the elongate support, as required by claim 26. In the response to arguments, the Examiner states that "the elongate member in Coates' device coupled to the arms is located at a proximal end of the device because all of the arm length extending from the elongate member downward can be considered distal to the elongate member and anything above the elongate member is at a proximal end. Thus, Applicant's argument that the elongate member is not coupled at a proximal end is mistaken since proximal and distal are relative terms." While Applicants agree that the terms proximal and distal *can* be relative terms, the Examiner seems to have overlooked the fact that the claim requires a proximal *end* of the arms to be coupled to the support. As explained above, the rod of Coates extends through a middle portion of the arms, thus a proximal *end* of the arm is not coupled to the rod.

Applicant further notes that it would not have been obvious to modify Coates to include a curved support because such a modification would change the principle operation of Coates. As explained in §2143.01(VI) of the *MPEP*, “[i]f the proposed modification or combination of the prior art would change the principle operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” The device of Coates includes two arms (151, 152) that are pivotally coupled to one another, and a threaded locking rod (155) extends through and threadably mates to the arms (151, 152) such that rotation of the locking rod (155) pivots the arms. In order to add the features of Phillips to the device of Coates, the locking rod would be altered to include a curve as taught in Phillips, which would render the device of Coates inoperable as it would be impossible to thread the curved rod through the arms in the configuration described in Coates. This modification would thus change the principle operation of Coates, and therefore would not have been obvious.

The Examiner has failed to provide the required motivation for making the modification described above to the device disclosed in Coates. The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. (See *MPEP* 2144). There is no advantage to adding a curvature to the rod as taught in Phillips to the Coates device because it would serve absolutely no purpose. Thus, altering the locking rod with a curve is useless and does not provide any additional advantage.

In *KSR*, the operative question when considering obviousness of a combination of known elements is “whether the improvement is more than the predictable use of prior art elements according to their established function.” The claimed invention is not a predictable use of Coates and Phillips according to their established function. As stated above, Coates discloses a drill guide with arms that are pivotally coupled to one other. The established function of the device of Coates is to hold a bone plate for coupling to the spine. Phillips, on the other hand, provides a tissue retractor. The established function of the Phillips device is to separate tissue at the site of a wound to allow access for surgical procedures. Since the established function of each reference is entirely distinct, it would not even be predictable to combine these two references. Replacing the arms of Coates in order to allow them to

slide along a rack at a proximal end thereof, as taught by Phillips' retractor, would completely alter the functioning of the device as required by Coates.

Accordingly, claims 1 and 26, and claims 3-8, 11, 12, 15-23, 28, 31, 33, 34, 36, 37, 46, and 48 which depend therefrom, distinguish over the combined references.

(3) German Patent No. 4201043 of Ulrich.

Claim 92 is rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over German Patent No. 4201043 of Ulrich. Claim 92 depends from claim 91, and thus distinguishes over Ulrich for at least the same reasons discussed above. Claim 92 therefore represents allowable subject matter at least because it depends from claim 91.

Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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